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COOLEY GODWARD LLP
ATTN: PATENT GROUP
11951 FREEDOM DRIVE, SUITE 1700
ONE FREEDOM SQUARE- RESTON TOWN CENTER
RESTON, VA 20190-5061

EXAMINER

SILVER, DAVID

ART UNIT	PAPER NUMBER
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2128

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,373

Applicant(s)

BRAZHNİK ET AL.

Examiner

David Silver

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4-21-04, 12-17-02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on June 13 2005, May 15 2002, December 17 2002, Feb 14 2002, April 21 2004 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- a. Claims 10-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.
- b. Specifically, claims 10-23 are not technologically embodied since the claims have not recited any limitations relating to a practical application in the technological arts and have merely claimed non-statutory subject matter (software). The examiner therefore submits that the application has not recited any limitations that provide a tangible result and have merely claimed software.
- c. Specifically, claims 10-23 recite "computer executable software code" comprising of code, which is non-statutory subject matter as being intangible (software code). As such, the claims are not limited to statutory subject matter and is therefore are non-statutory. The examiner

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respectfully suggests that claim 10, 16, and 20 be further limited by having a physical embodiment. The examiner respectfully suggests that claims be further limited to **tangible** computer readable medium.

Section 2106 [R-2] (Patentable Subject Matter – Computer-Related Inventions) of the MPEP recites the following: “Data structures not claimed as embodied in computer-readable media are descriptive material per se and are not statutory because they are not capable of causing functional change in the computer. See, e.g., Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760.”

d. As such, the claim is not limited to statutory subject matter and is therefore non-statutory.

The examiner therefore submits that Applicant's have not recited any limitations that provide a tangible embodiment and have merely **claimed software**, which is not tangibly embodied.

An invention which is eligible for patenting under 35 U.S.C 101 is in the “useful arts” when it is a machine, manufacture, process or composition of matter, which produces a concrete, **tangible**, and useful result.

“Tangible” – Applying In re Warmerdam, 33 F.3d 1354, 31 USPQ2d 1754 (Fed. Cir. 1994), the examiner will determine whether

i. there is simply software which is not tangibly embodied in a matter so as to be executed;

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The examiner respectfully submits, under current PTO practice, that the claimed invention does not recite a tangible embodiment and is merely drawn to non-statutory subject matter (software code).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-9, 20, 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Volker Tresp ("Tresp" hereinafter) (US Patent 6,272,480).

b. As per claim 1, Tresp discloses a method for creating a computer model of diabetes, comprising:

- ii. identifying data relating to diabetes, the data relating changes in biological states to biological attributes of diabetes
(col.: 1 lines: 18-29, column: lines: 2 lines 23-28 "influence variables");
- iii. identifying a plurality of biological processes related to the data, the plurality of biological processes defining at least one

portion of the disease state of diabetes (col.: 2 lines: 24-26, col.: 4 lines: 33-41 “quantity of food” in the reference is directly related to the quantity of protein, referring to disease state, col. 4 lines 24-26: to warn a person a portion of the, or the whole, simulation result is used in conjunction with reference material to identify whether the said result is “showing” the disease state); and

iv. combining the plurality of biological processes to form a simulation of glucose metabolism in the context of multiple macronutrient metabolism (col.: 2 lines: 10-22, col.: 4 lines: 33-41 multiple macronutrient metabolism correlates to “carbohydrates” within the reference).

c. As per claim 2, Tresp discloses a method of claim 1, further comprising:

v. producing a simulated biological attribute associated with at least one biological attribute of diabetes from the combined plurality of biology processes based on the combined plurality of biology processes (col.: 2 lines: 10-22);

vi. comparing the simulated biological attribute with a corresponding biological attribute associated with a reference pattern of diabetes (col.: 6 lines: 49-52, “risk analysis” inherently involves reference data taken from taken in a control environment from a diseased biological system, such

data is then analyzed and compared to new/simulated result to assess the risks); and

identifying the computer model as a valid computer model of diabetes if the simulated biological attribute is substantially consistent with the biological attribute associated with a reference pattern of diabetes (**col.: 1 lines: 45-50 The computer model would inherently be substantially consistent when using a neural network and sufficient training data. As such it would be a valid model given its consistency to the reference pattern.**)

d. As per claim 3, Tresp discloses a method of claim 1, wherein the combining the plurality of biological processes includes:

vii. forming a first mathematical relation among biological variables associated with a first biological process from the plurality of biological processes (**col.: 3 equation 1**); and

viii. forming a second mathematical relation among biological variables associated with the first biological process and a second biological process from the plurality of biological variables associated with the plurality of biological processes (**col.: 3 equation 2 Additionally, their associatively is shown in equation 3**).

e. As per claim 4, Tresp discloses a method of claim 3, further comprising:

ix. creating a set of parametric changes in the first mathematical relation and the second mathematical relation (**col.: 5 lines: 44-49 training data, when introduced into the neural network will serve as a parametric change in the mathematical relations**); and

x. producing a simulated biological attribute based on at least one parametric change from the set of parametric changes, the simulated biological attribute being substantially consistent with at least one biological attribute associated with a reference pattern of diabetes (**col.: 5 lines: 59-61, col.: 6 lines: 32-36, col.: 1 lines: 45-50 The computer model would inherently be substantially consistent when using a neural network and sufficient training data. As such it would be a valid model given its consistency to the reference pattern.**).

f. As per claim 5, Tresp discloses a method of claim 3, further comprising:

xi. creating a set of parametric changes in the first mathematical relation (**col.: 5 lines: 44-49 training data, when introduced into the neural network will serve as a parametric change in the mathematical relations**)

xii. and a set of parametric changes in the second mathematical relation, the set of parametric changes in the first mathematical relation being associated with a first diabetes defect having its own

degree of severity (**col.: 5 lines: 59-61, col.: 6 lines: 32-36, col.: 1 lines: 45-50** The computer model would inherently be substantially consistent when using a neural network and sufficient training data. As such it would be a valid model given its consistency to the reference pattern.),

xiii. the set of parametric changes in the second mathematical relation being associated with a second diabetes defect having its own degree of severity (**col.: 4 lines: 33-41, col.: 5 lines: 59-61**).

The Examiner asserts that, according to column 5 lines 59-61, a mathematical equation is used it is inherent that variables within the formula contain magnitudes. Thus, it is inherent that the magnitudes are actually severity. Hereinafter, the Examiner asserts that Application's "severity" is in fact measurable within the mathematical formula. Therefor, it is inherently included in all math-based simulators wherein the inputs have variable magnitudes.

g. As per claim 6, Tresp discloses a method of claim 3, further comprising

xiv. converting at least one biological variable from the group of the first mathematical relation or second mathematical relation into a biological variable that evolves over time (**col.: 1 lines: 51-61 with emphasis on 55-57 "modeled in the form of a time series"**); and

xv. producing a series of simulated biological attributes based on the converted biological variable the series of simulated biological attributes being substantially consistent with a corresponding biological attribute associated with a reference pattern of diabetes, the series of simulated biological attributes representing the disease progression in the reference pattern of diabetes (**col.: 6 lines: 49-52, col.: 1 lines: 45-50 The computer model would inherently be substantially consistent when using a neural network and sufficient training data. As such it would be a valid model given its consistency to the reference pattern.**).

h. As per claim 7-9, the claims differ only in statutory basis to claims 1-3 (7-9 are the product for the method of claims 1-3).

i. As per claim 20, Tresp discloses a computer executable software code, comprising:

xvi. code to define a plurality of biological processes related to a disease state of diabetes including (**col.: 2 lines: 38-41 because the neural network is computerized it is inherent that code is used in order to define the formulas associated with the biological processes**):

(1) code to define a set of mathematical relations associated with a first biological process from the plurality of biological processes and associated with interactions among

biological variables associated with the first biological process (**col.: 3 equation 1**), and

(2) code to define a set of mathematical relations associated with a second biological process from the plurality of biological processes and associated with interactions among biological variables associated with the second biological process (**col.: 3 equation 2**),

xvii. a first biological process from the plurality of biological processes being associated with metabolism of at least two from the group of carbohydrates, fats and proteins, a second biological process from the plurality of biological processes being associated with metabolism of glucose (**col.: 2 lines: 10-23, col.: 4 lines: 33-41**).

j. As per claim 25, Tresp discloses a method for creating a computer model of diabetes, comprising:

xviii. identifying data relating to diabetes, the data relating changes in biological states to biological attributes of diabetes (**col.: 1 lines: 48-50 since the influencing variables are measured they are also inherently identified**);

xix. identifying a plurality of biological processes related to the data, the plurality of biological processes defining at least one portion of the disease state of diabetes (**col.: 2 lines: 24-26, col.: 4 lines: 33-41 "quantity of food" in the reference is directly**

related to the quantity of protein, referring to disease state, col. 4 lines 24-26: to warn a person a portion of the, or the whole, simulation result is used in conjunction with reference material to identify whether the said result is “showing” the disease state); and

xx. combining the plurality of biological processes to form a simulation of at least one biological attribute of diabetes in the context of fat metabolism (col. 3 equation 3, col.: 2 lines: 10-23, col.: 4 lines: 33-41 **Tresp’s disclosure is broader than the limitations set forth by this claim. Hence, it covers biological attributes of diabetes in the context of fat metabolism.**).

k. As per claim 26, Tresp discloses a method for creating a computer model of diabetes, comprising:

xxi. identifying data relating to diabetes, the data relating changes in biological states to biological attributes of diabetes (col.: 1 lines: 48-50 **since the influencing variables are measured they are also inherently identified**);

xxii. identifying a plurality of biological processes related to the data, the plurality of biological processes defining at least one portion of the disease state of diabetes (col.: 2 lines: 24-26, col.: 4 lines: 33-41 **“quantity of food” in the reference is directly related to the quantity of protein, referring to disease state, col. 4 lines 24-26: to warn a person a portion of the, or the**

whole, simulation result is used in conjunction with reference material to identify whether the said result is “showing” the disease state); and

xxiii. combining the plurality of biological processes to form a simulation of at least one biological attribute of diabetes in the context of protein metabolism (**col. 3 equation 3, col.: 2 lines: 10-23, col.: 4 lines: 33-41 Tresp’s disclosure is broader than the limitations set forth by this claim. Hence, it covers biological attributes of diabetes in the context of protein metabolism.**).

I. As per claim 27, Tresp discloses a computer model of a disease state of diabetes, comprising:

xxiv. a computer-readable memory storing (**col.: 2 lines: 38-41**

See Examiner assertion below):

(3) instructions defining a set of biological processes related to the disease state of diabetes (**col.: 2 lines: 38-41 See Examiner assertion below),**

(4) at least two biological processes from the set of biological processes being associated with a set of mathematical relationships related to interactions among biological variables associated with the biological processes (**col. 3, equations 1-3, col.: 4 lines: 33-41 it is inherent that the biological processes described by equations 1-3 are associated the said equations. As such, the reverse,**

in this case, also holds true. Since equation 3 is the combination of equation 1 and 2, there is an interaction and a relationship formed between the said two equations.),

(5) the instructions defining a simulation of at least one biological attribute of diabetes in the context of fat metabolism (col. 3 equation 3, col.: 2 lines: 10-23, col.: 4 lines: 33-41 Tresp's disclosure is broader than the limitations set forth by this claim. Hence, it covers biological attributes of diabetes in the context of fat metabolism.); and

(6) a processor coupled to the computer-readable memory, the processor configured to execute the instructions (col.: 2 lines: 38-41 See Examiner assertion below).

Examiner assertion: Tresp is describing a neural network operating on a computer ("computerized neural network"). A computer inherently has a *processor to execute instructions* and for instructions to be executed. It is inherent that the instructions are first stored in *memory* in order to be executed.

m. As per claim 28, Tresp discloses a computer model of a disease state of diabetes, comprising:

xxv. a computer-readable memory storing (col.: 2 lines: 38-41

See Examiner assertion above):

(1) instructions defining a set of biological processes related to the disease state of diabetes (col.: 2 lines: 38-41

See Examiner assertion above),

(2) at least two biological processes from the set of biological processes being associated with a set of mathematical relationships related to interactions among biological variables associated with the biological processes (col. 3, equations 1-3, col.: 4 lines: 33-41 it is inherent that the biological processes described by equations 1-3 are associated the said equations. As such, the reverse, in this case, also holds true. Since equation 3 is the combination of equation 1 and 2, there is an interaction and a relationship formed between the said two equations.),

(3) the instructions defining a simulation of at least one biological attribute of diabetes in the context of protein metabolism (col. 3 equation 3, col.: 2 lines: 10-23, col.: 4 lines: 33-41 Tresp's disclosure is broader than the limitations set forth by this claim. Hence, it covers biological attributes of diabetes in the context of protein metabolism.); and

(4) a processor coupled to the computer-readable memory, the processor configured to execute the instructions (**col.: 2 lines: 38-41 See Examiner assertion below**).

Examiner assertion: Tresp is describing a neural network operating on a computer (“computerized neural network”). A computer inherently has a *processor to execute instructions* and for instructions to be executed. It is inherent that the instructions are first stored in *memory* in order to be executed.

4. Claims 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Stephen Brown (“Brown” hereinafter) (US Patent 5,956,501).

b. As per claim 10, Brown discloses a computer executable software code, comprising:

ii. code to define a normal biological state through a set of biological processes, each biological process from the set of biological processes having its own associated parameter set, the set of biological processes being related to glucose metabolism in the context of multiple macronutrient metabolism (**col.: 6 line: 5 $X(t_j)$ refers to biological state at time t_j ; wherein, $R(t_j)$ and $R(t_i)$ is the set of biological processes and each process has its own associated parameter ‘t’, col. 1 lines 15-20 with emphasis on line 16**);

iii. code to provide a plurality of predefined defect indicators, each predefined defect indicator from the plurality of predefined defect indicators being uniquely associated with a defect from a plurality of defects associated with a disease state of diabetes, each defect from the plurality of defects being associated with at least one biological process from the set of biological processes **(col.: 4 top table. Predefined defect indicators are shown in column 2 of the table); and**

iv. code to receive a user-specified identification of a first defect indicator from the plurality of predefined defect indicators, a first defect from the plurality of defects being associated with the first defect indicator, the parameter set associated with each biological processes that is associated with the first defect being changed based on the user-specified identification **(col. 2 lines 57-59, col. 4 lines 58-61 input device for entering data, col.: 4 lines: 17-19 the self-care parameters would be entered by the user. Each defect ("self-care parameter") is associated with an input value, "parameter set" with each biological process (column 7, lines 60-62 "metabolism rate"))).**

c. As per claim 11, Brown discloses a computer executable software code of claim 10, further comprising:

v. code to determine at least one simulated biological attribute based on the modified biological process associated with the first

defect, the simulated biological attribute being substantially consistent with at least one corresponding biological attribute associated with diabetes in a reference pattern of diabetes (col.: 8 line: 38).

Examiner asserts that it is inherent that Brown's disclosed computer system performing the simulation has code to do the above reference limitations, as mentioned by Brown in abstract 4th line from the bottom.

d. As per claim 12, Brown discloses a computer executable software code of claim 10, further comprising:

vi. code to receive a user-specified identification of a second defect indicator from the plurality of predefined defect indicators, a second defect from the plurality of defects being associated with the second defect indicator, the parameter set associated with each biological processes that is associated with the second defect being changed based on the user-specified identification (col. 2 lines 57-59, col. 2 lines 57-59, col.: 4 lines: 17-19 the self-care parameters would be entered by the user. Each defect ("self-care parameter") is associated with an input value, "parameter set" with each biological process (column 7, lines 60-62 "hepatic and peripheral insulin sensitivities"))).

Examiner asserts that it is inherent that Brown's disclosed computer system performing the simulation has code to do

the above reference limitations, as mentioned by Brown in abstract 4th line from the bottom.

e. As per claim 13, Brown discloses a computer executable software code of claim 12, wherein:

vii. the first defect has an associated severity based on the change to the at least one associated parameter set (**col.: 7 line 66 to col.8 line 1 K_m refers to the associated severity**); and

viii. the second defect has an associated severity based on the change to the at least one associated parameter set, the severity associated with the first defect being different from the severity associated with the second defect (**col.: 8 lines: 1-6 " K_1 " and " K_3 ".**

f. As per claim 14, Brown discloses a computer executable software code of claim 12, wherein:

ix. the first defect has an associated severity based on the change to the at least one associated parameter set (**col.: 7 line 66 to col.8 line 1**); and

x. the second defect has an associated severity based on the change to the at least one associated parameter set, the severity associated with the first defect being substantially similar to the severity associated with the second defect (**col.: 8 lines: 1-6 " K_1 " and " K_3 ".**

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The examiner asserts that a something "similar" is inherently non-identical to something else, as given by the definition of the word similar:

similar: Related in appearance or nature; alike though **not identical**.

(Source: <http://www.answers.com/similar&r=67>)

Therefore, the examiner finds that claim 14 is a duplicate of claim 13.

g. As per claim 15, Brown discloses a computer executable software code of claim 10, further comprising:

xi. code to produce a simulated biological attribute based on the parameter set associated with each biological processes that is associated with the first defect (**col.: 2 lines: 32-34**), the simulated biological attribute being substantially consistent with biological attributes of a reference pattern of diabetes (**col.: 2 lines: 10-13, col.: 7 lines: 22-30** **The simulation would inherently be substantially consistent when using Brown's disclosed method and apparatus with sufficient input data. As such it would be a valid model given its consistency to the reference pattern.**).

2. Claims 16-19, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by David Rivonelli, "Rivonelli" hereinafter, (U.S. Patent 6,246,975).

h. As per claim 16, Rivonelli discloses a computer executable software code, comprising:

code

(1) to provide a plurality of predefined defect indicators, each predefined defect indicator from the plurality of predefined defect indicators being uniquely associated with a defect from a plurality of defects associated with a disease state, each defect from the plurality of defects being associated with at least one biological process from a set of biological processes (col.: 16 lines: 17-18, col.: 23 lines: 30-36 **When the generation method is performed, it provides a description of all of the findings (defects)),**

(2) the set of biological processes being related to glucose metabolism in the context of multiple macronutrient metabolism (col.: 12 lines: 63-67)

code

(1) to receive a user-specified identification of a first defect indicator from the plurality of predefined defect indicators, a first defect from the plurality of defects being associated with the first defect indicator, the first defect being associated with at least one biological process and its associated parameter set, the at least one parameter set associated with the first defect being changed based on the

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user-specified identification; (col.: 12 lines: 50-52, col.: 8 lines: 22-26 "user-specified" because the information is collected then transferred into computer readable format, col.: 16 lines: 17-18 findings correlate to defects, col. 15 lines 64-67 wherein the second defect may be "cardiovascular disease"), and

code

(1) to receive a user-specified identification of a second defect indicator from the plurality of predefined defect indicators, a second defect from the plurality of defects being associated with the second defect indicator, the second defect being associated with at least one biological process and its associated parameter set, the at least one parameter set associated with the second defect being changed based on the user-specified identification (col.: 12 lines: 50-52, col.: 8 lines: 22-26 "user-specified" because the information is collected then transferred into computer readable format, col.: 16 lines: 17-18 findings correlate to defects, col. 15 lines 64-67 wherein the second defect may be "disease of glucose intolerance").

The Examiner asserts that a change in one biological processes of an individual will very least be associated with another biological process for the fact that it is in the same

individual. As such their associatively will be generated by being "part" of one entity.

i. As per claim 17, Rivonelli discloses a computer executable software code of claim 16, wherein:

xii. the first defect having an associated severity based on the change to the at least one associated parameter set (**col.: 12 lines: 12-21**),

xiii. the second defect having an associated severity based on the change to the at least one associated parameter set, the severity associated with the first defect being different from the severity associated with the second defect (**col.: 12 lines: 12-21, col.: 13 lines: 51-53**).

j. As per claim 18, Rivonelli discloses a computer executable software code of claim 16, further comprising:

xiv. code to define a normal biological state through the set of biological processes, each biological process from the set of biological processes being associated with its own parameter set (**col.: 22 lines: 60-65**).

k. As per claim 19, Rivonelli discloses a computer executable software code of claim 16, wherein

xv. the plurality of defects are associated with type 2 diabetes (**col.: 6 lines: 58-62**).

n. As per claim 24, Rivonelli discloses a method for creating a computer model of diabetes, comprising:

xxvi. receiving a plurality of user-selected indications to define a plurality of biological processes, each biological process from the plurality of biological processes being based on data that relates to changes in biological states to biological attributes of diabetes **(col.: 12 lines: 50-52, col.: 8 lines: 22-26 "user-specified" because the information is collected then transferred into computer readable format, col.: 16 lines: 17-18 findings correlate to defects, col. 15 lines 64-67 wherein the second defect may be "cardiovascular disease")**;

xxvii. producing a representation of the plurality of biological processes based on the user-selected indications, the plurality of biological processes defining at least one portion of the disease state of diabetes **(Abstract lines 1-4, The Examiner asserts that "reproducing a representation ... based on the user-selected indications" means simulating the system based on user inputs**;

xxviii. producing a simulated biological attribute associated with at least one biological attribute of diabetes based on the combined plurality of biology processes **(col.: 13 lines: 51-53, Abstract lines 1-4)**; and

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I. assessing a validity of the computer model based on a comparison between the simulated biological attribute and a corresponding biological attribute associated with a reference pattern of diabetes (**Abstract 1-4 “simulating” The computer model would inherently be substantially consistent because it uses predetermined criteria as well as user-input as input into the simulation program. Additionally, the Examiner asserts that the assessment can be performed by the examinee and as such references column 12, lines 50-52 with emphasis on the examinee’s conclusion about the simulation.**).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

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35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volker Tresp ("Tresp" hereinafter) (US Patent 6,272,480) as applied to claim 20 above, and further in view of David Rivonelli, Rivonelli hereinafter, (U.S. Patent 6,246,975).

m. As per claim 21, Tresp substantially discloses the computer executable software code of claim 20, including code to define a set of parametric changes for a biological process (**Tresp, col.: 5 lines: 44-49 training data, when introduced into the neural network will serve as a parametric change in the mathematical relations**). Tresp does not specifically disclose the code to receive user-specified identification of a first defect indicator.

However, Rivonelli discloses an analogous system that includes steps to receive a user-specified input of a defect indicator (**Rivonelli, col.: 8 lines: 22-26 "user-specified" because the information is collected then transferred into computer readable format, col.: 16 lines: 17-18 findings correlate to defects, col. 15 lines 64-67 wherein the a defect may be "cardiovascular disease"**). It would have been obvious to one of ordinary skill in the art of disease modeling, at the time of the present invention, to combine the teachings of the cited references. In fact, motivation combine would have been to allow the examinee to have a

much simple interface through the set of predefined findings (defect indicators) in order to lessen the amount of work needed to be performed by the examinee or physician.

n. As per claim 22, Rivonelli discloses a computer executable software code of claim 21, further comprising:

- i. code to receive a user-specified identification of a second defect indicator from the plurality of predefined defect indicators, the second defect indicator from the plurality of defect indicators being uniquely associated with a second defect from the plurality of defects that is associated with the disease state of diabetes, the second defect being associated with at least one biological process and its associated parameter set, the at least one parameter set associated with the second defect being changed based on the user-specified identification (**col.: 12 lines: 50-52, col.: 8 lines: 22-26 "user-specified" because the information is collected then transferred into computer readable format, col.: 16 lines: 17-18 findings correlate to defects, col. 15 lines 64-67 wherein the second defect may be "disease of glucose intolerance"**).
- ii. the first defect having an associated severity based on the change to the at least one associated parameter set, the second defect having an associated severity based on the change to the at least one associated parameter set, the severity associated with

the first defect being different from the severity associated with the second defect (**col.: 12 lines: 12-21, col.: 13 lines: 51-53**).

2. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Volker Tresp ("Tresp" hereinafter) (US Patent 6,272,480) as applied to claim 20 above, and further in view of AIDA Case Selector and AIDA Explanations (See IDS for reference information).

b. As per claim 23, Tresp does not specifically discuss the limitations of the claim. However, AIDA implemented an analogous system having

iii. code to receive a user selection of a link representation from a set of predefined link representations, each predefined link representation in the set of predefined link representations being associated with a different mathematical relationship, the user-selected link representation being associated with the interrelationship between a first biological variable and a second biological variable (**AIDA Case Selector, page: 3 reference 1, page 4 reference 2**),

iv. a first link representation from the set of predefined link representations being a representation of the first biological variable having an effect on the second biological variable (**AIDA Explanations, page 3, Section "Blood glucose level (BGL)"**),

v. a second link representation from the set of predefined link representations being a representation of instances of the first biological variable being converted to instances of the second

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biological variable (**AIDA Explanations, page 1, Section "Blood glucose units"**).

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Reference U and V discuss modeling of diabetes through the use of computers and input parameters and therefore apply to claims 1-28.

4. Claims 1-28 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Silver whose telephone number is (571) 272-8634. The examiner can normally be reached on Monday thru Friday, 8am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jean Homere can be reached on (571)272-3780. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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David Silver
Examiner
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